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Ballard Spahr Andrews & Ingersoll, LLP
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

| EXAMINER | |
|---|---|
| HURT, SHARON L | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/591,725 | LEONARD, JOAN D. | |
| | Examiner | Art Unit | |
| | SHARON HURT | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *9/5/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-23 are pending and under examination. Claim 12 is currently amended and claim 23 is new.

### *Claim Objections*

2. Claim 21 is objected to because of the following informalities: The claim contains "22." at the end of the claim. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 13-17 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Schat et al. (US Patent 5,965,139 (1999)).

Schat teaches a CIAV vaccine comprising live CIAV grown in MSB-1 cells (column 5, lines 23-44 and column 6, lines 31-43) (*as it relates to claim 1*). Schat teaches the vaccine can be administered to chicken embryos in ovo (column 5, lines 35-47) (*as it relates to claim 6*). Schat teaches the vaccine may be injected directly into embryos between 17 and 21 days of incubation (column 5, lines 35-38) (*as it relates to claims 4, 6, 7 and 17*). Because vaccinating chickens greater than 28 days of age (*as it relates to claim 5*) is only vaccinating a chicken a week older, which further would be more developmentally mature, reasonably vaccinating older

chickens would be equally as safe or safer than vaccinating the younger chickens immunized by Schat. Schat teaches the vaccine may be live or inactivated (column 17, lines 38-42) (*as it relates to claim 8*). Schat teaches an immunogenic vaccine used as prophylactic and/or therapeutic against CIAV when administered to chickens (column 16, lines 35-39 and column 17, lines 55-57) (*as it relates to claim 13*). Schat teaches the vaccines comprising live microorganism are attenuated or treated so that it does not cause disease by itself (column 17, lines 55-57) (*as it relates to claims 1-3*). Schat teaches a method of immunization wherein the CIAV vaccines are protective against CIAV (column 2, lines 61-67) (*as it relates to claims 14-15*). Schat teaches exposing chickens to CIAV may induce maternal antibodies in chickens which may help protect against CIAV infections in their progeny (column 2, lines 29-31) (*as it relates to claim 16*). Schat teaches in their method of making a recombinant vaccine that additional polypeptides, thus multiple antigens, can be combined in their vaccine against CIAV and against another poultry disease such as Newcastle diseases virus (column 18, lines 13-28) (*as it relates to claim 18*). Schat teaches the vaccine may be administered intradermal, intramuscular, intraperitoneal, intravenous, subcutaneous, ocular (ocular can be spray), intranasal and oral administration (oral administration can be drinking water) (column 17, lines 6-13) (*as it relates to claims 19-22*).

It is routinely practiced in the art that vaccines are not used that cause disease in the immunized subject. Therefore the CIAV vaccine taught by Schat does not reasonably cause Marek's disease or illness in chicken embryos, absent evidence to the contrary. Thus, Schat further anticipates this limitation of claim 1.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 13-17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schat et al. in view of Cardona et al. (Avian Diseases, July 2000, Vol. 44(3), p. 661-667).

The teachings of Schat are set forth supra **however** Schat does not teach a CIAV vaccine is administered to chickens greater than 28 days of age.

Cardona teaches a vaccine against chicken infectious anemia virus (CIAV) comprising a commercial live vaccine (Abstract). The limitation of "passaged in MSB-1 cells" is being viewed as an intended method of culturing the CIAV of the present invention, thus this limitation confers no further substance to the structure of the present composition/ product and is given little patentable weight. Because the reference is silent on this issue, the commercial vaccine is considered to be free of contamination of other viruses in absence of evidence to the contrary. Cardona also teaches a method of immunizing the chickens at 44 days of age by administering a modified live CIAV vaccine intramuscularly (page 663, 2nd column) (*as it relates to claim 5*). However Cardona does not teach a method of preparing a CIAV vaccine.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to complement the vaccine strategy of Schat by vaccinating the chickens about one month of age because Cardona teaches administering a modified live CIAV at 44 days of age with a reasonable expectation of success.

5. Claims 1-9 and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schat et al. in view of Cardona et al. as applied to claims 1-8, 13-17 and 19-22 above, and further in view of Rosenberger et al. (Avian Diseases, Oct. – Dec. 1989, Vol. 33, No. 4, pages 707-713).

The teachings of Schat and Cardona are described above wherein Schat teaches a method of making a CIAV vaccine. However, neither reference teaches a method of making a CIAV vaccine comprising removing or killing any Marek's disease virus present in the MSB-1 cells (i.e., as it relates to claim 9).

Rosenberger teaches a method of cultivating chicken anemia agent (CAA) (*CIAV*) which was isolated and separated from Marek's disease virus (MDV) (page 707, Abstract and last paragraph) (*as it relates to claim 9*). Rosenberger teaches the isolate was filtered through a 50 nm and 25 nm filter and has stability at 56°C (Abstract, page 708, last paragraph and page 709, 1st paragraph). Rosenberger also teaches the CAA (*CIAV*) was purified by inactivating the MDV with chloroform (page 708, 2nd paragraph) (*as it relates to claim 9*). Rosenberger further teaches CAA (*CIAV*) is less than 50 nm in diameter and difficult to propagate in vitro in primary and secondary chicken embryo fibroblast (CEF) cells, VERO, CRFK, MDCK and A-72 continuous cell lines (page 711, 1st column). However, Rosenberger does not teach a method of preparing a CIAV vaccine.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to separate CIAV from MDV because it is known that MSB-1 cells are derived from a MDV cell line and Rosenberger teaches a method of isolating CIAV from MDV with a reasonable expectation of success.

6. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schat et al. in view of Cardona et al. and Rosenberger et al. as applied to claims 1-8 and 13-22 above, and further in view of Calnek et al. (Avian Diseases, Jul-Sep 1971, Vol. 15, No. 3, pages 508-517).

The teachings of Schat, Cardona and Rosenberger are described above. Schat teaches of method of preparing CIAV in MSB-1 cells and preparing a vaccine composition. However, none of the references teach using freezing and thawing cycles followed by 37°C incubation to remove Marek's disease or filtering the MSB-1 cells through a 5 micron filter.

Calnek teaches methods of preparing Marek's Disease Virus (MDV) and characteristics of MDV including infectivity and neutralization (Abstract). Calnek teaches MDV isolated were exposed to freeze-thaw cycles followed by warming to 37°C (page 511, Freeze-thaw cycles) (*as it relates to claim 10*). Calnek teaches infectious MDV survived 4 freeze-thaw cycles without a titer reduction (page 513, Freeze-thaw cycles) but when incubated at 37°C for several days the virus was killed (page 512, Graph 37°C) (*as it relates to claims 10 and 12*). Calnek also teaches that MDV was not able to pass through a 220μm size filter (page 514, Filtration and Table 4) (*as it relates to claims 11 and 23*). It is a reasonable assumption that the vaccine against CIAV taught by Schat, Cardona and Rosenberger does not cause MDV in chickens immunized with the vaccine, absent evidence to the contrary. However, Calnek does not teach a method of preparing a CIAV vaccine.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a method known in the art to inactivate MDV such as freeze and thaw cycles followed by incubation at 37°C because Calnek teaches MDV was killed by this

process with a reasonable expectation of success based on the teachings of the prior art. In addition it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use filtration to remove MDV because Calnek teaches MDV is a larger virus than CIAV and used a filter with a reasonable expectation of success.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

-Fulton et al. (Avian Diseases, Jan-Mar 2000, Vol. 44, No. 1, pages 8-16) teaches the effects of route of vaccination in chickens by eyedrop, spray, and in drinking water (Abstract). Fulton teaches the administration methods given by eyedrop and spray produced higher virus titer (Abstract) (*as it relates to claims 19 and 21*).

## ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M, T, Th, F 8:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Hurt/
Examiner, Art Unit 1648
August 20, 2009

/Robert C. Hayes, Ph.D./
Primary Examiner, Art Unit 1649